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CUSTOMER NO.: 24737

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of STECKNER, et al.	Examiner: H. NGUYEN
Serial No.: 10/573,727	Art Unit: 3768
Filed: March 7, 2007	Confirmation: 2265
For: **TARGET TRACKING METHOD AND APPARATUS FOR RADIATION TREATMENT PLANNING AND DELIVERY**	
Date of Last Office Action: November 2, 2010	
Attorney Docket No.: PHUS030393US2 /PKRZ 201603US01	Cleveland, OH 44114 December 30, 2010

REPLY BRIEF

Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Reply Brief is responsive to the Examiner's Answer of November 2, 2010.

The Examiner's Answer raises no new issues with respect to Sections (1)-(9) and (11). In Section (9) Grounds of Rejection, the Examiner merely repeats the language of the Final Rejection of January 22, 2010. Because the Examiner raises no new issues in these sections of the Examiner's Answer, no response to these Sections is appropriate or permitted. Section (10) Response to Argument of the Examiner's Answer is new, and is addressed below.

CERTIFICATE OF ELECTRONIC TRANSMISSION

I certify that this **REPLY BRIEF** and accompanying documents in connection with U.S. Serial No. 10/573,727 are being filed on the date indicated below by electronic transmission with the United States Patent and Trademark Office via the electronic filing system (EFS-Web).

12-30-2010
Date

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(10) RESPONSE TO ARGUMENTS

The Examiner's comments addressing claims 1 and 6 do not accurately interpret the Schweikard reference. The Examiner asserts that the patient is the target. This interpretation is inconsistent with Schweikard, in which the target 151 is a much smaller region within the patient. The embodiment of Schweikard upon which the Examiner relies is directed to a radiation therapy device in which a LINAC directs a target beam of ionizing radiation precisely at the target region 151, such as a tumor. In the paragraph which starts at column 7, line 31 and in the representation of Figure 9A, the target region or tumor is represented as a sphere 200. As Schweikard explains in conjunction with Figures 9B and 9C, in order to be sure that the target region is fully treated, e.g., the tumor is killed, even if there is motion, then a much larger safety margin 202 must be irradiated as well. As Schweikard notes in column 7, irradiating a larger spherical target causes the amount of radiation dose to go up by a power of 3. For example, if the radius of the safety margin 202 is twice the radius of the target 200, then the amount of radiation delivered increases by a factor of 2^3, i.e., 8. The amount of tissue irradiated with lethal doses of radiation also increases by a like factor. The large safety margins as illustrated in Figures 9B and 9C, is a problem. As Schweikard notes, killing such a large amount of healthy tissue is not good or desirable. It is the object of Schweikard to compensate for motion so accurately that the safety margin can be reduced to almost the size 200 of the target as shown in Figure 9D. It is submitted that it is inappropriate to interpret the patient as the target to which the lethal dose of radiation is delivered during the radiation therapy process.

Schweikard uses surgically implanted markers 152 to determine the location of the target with satisfactory accuracy. Although the paragraph which starts at column 6, line 51 does describe the use of an external marker 180 which monitors breathing, for example, Schweikard at column 6, line 66 – column 7, line 5 clearly states that such the external marker 180 cannot accurately reflect the motion of the target organ. Rather, the surgically implanted markers 152 are necessary for the accurate and satisfactory functioning of the Schweikard device. Stated another way, Schweikard specifically teaches against the use of only external markers 180.

The Examiner further argues that Schweikard discloses an MRI localizer. When one understands the radiation therapy process, it is clear that

Schweikard does not disclose an MRI localizer. The radiation therapy process starts by generating a high resolution three-dimensional image of a region of a subject in which the tumor or other target is suspected. This high resolution 3D image is typically sectioned to identify the tumor or target region to be irradiated and to identify other regions which should not be irradiated or to which minimal amounts of radiation should be applied. It should be remembered that the radiation beam from the LINAC typically goes through the subject. To deliver the prescribed dose to the target, but not to all of the other tissue along the trajectory, the target is irradiated for short periods from a plurality of directions. The directions and the amount of radiation applied along each direction or trajectory is carefully planned to assure that the prescribed dose of radiation is delivered to the target and the safety margin 202 (accounting for attenuation along the trajectory), while assuring that an appropriately low dose is applied to other adjoining and nearby tissue. The CT or MR image alluded to in columns 2 and 4 of Schweikard referenced by the Examiner refer to this planning image. The stereotaxic radiation sources 30, 32, 160, 162 and detectors 34, 36, 168, 170 generate orthogonal projections of the surgically implanted internal markers 152 in order to determine the location of the surgically implanted internal markers, hence the target, precisely even if the patient moves. The Examiner fails to point to any section of Schweikard which suggests an MRI alternative to the stereotaxic x-ray sources of Schweikard. It might further be noted that the paragraph which begins at column 5, line 49 of Schweikard describes the internally implanted markers 152 as being gold, which is suitable for stereotaxic x-ray imaging as well as ultrasound. Because magnetic resonance imaging is based on resonance, typically hydrogen dipole resonance, gold is not imaged by commercially available magnetic resonance imaging systems. Moreover, the rapid switching of the magnetic field gradients in MRI imaging can induce eddy currents in metal objects, which eddy currents cause heating which could heat metal markers to such a high temperature that they cause injury to the surrounding tissue.

Also regarding claims 1 and 6, the Examiner asserts that the positional relationship between the external markers 180 and the target region is the same as the internal markers and the target region. Schweikard in the paragraph starting at column 6, line 66, categorically states that the relationship is not the same.

In the Examiner's arguments regarding claim 3, the appellant again asserts that the external marker 180 of Schweikard is not adequate to and is not used by Schweikard to determine the location of the target and aim the LINAC radiation treatment device. As is well-known to those skilled in this art, the respiratory cycle can be described as a sine wave with plateaus at the maximum and minimum. That is, when the patient is at full inhale or full exhale, the abdominal cavity remains relatively stationary; whereas, when the patient is inhaling or exhaling, the abdominal cavity is moving relatively quickly. Schweikard indicates that the stereotaxic x-ray system which monitors the surgically implanted internal markers 152 is pulsed. After all, the stereotaxic x-ray system is exposing the patient to x-rays, and it is advantageous to minimize the dose. It is submitted that one can use the respiratory state of the patient, for example, to control the pulsing rate of the stereotaxic x-ray system of Schweikard. However, as Schweikard clearly points out in numerous places, including the paragraph which starts at column 6, line 66, the surgically implanted internal markers are necessary for determining the location of the target with acceptable accuracy.

Also regarding claim 3, the appellant disagrees with the Examiner's assertion that the x-ray beam generator 30, 32, 160, or 162 is an interventional tool. Rather, the radiation beam which treats the target is generated by the LINAC 20.

In the Examiner's comments addressing claim 4, the Examiner erroneously interprets column 2, lines 10-65 and column 4, lines 20-24. The CT and MRI images referenced in these sections of Schweikard refer to the planning image for planning the radiation therapy and are not images which are taken repeatedly with such short time intervals that they can be used to track motion.

Regarding the Examiner's remarks addressing claim 5, it should be noted that claim 1 calls for an MRI apparatus for generating MR images of a subject disposed within an examination region. Claim 5 calls for a focused ultrasound ablator to be disposed within the examination region. Accordingly, it is submitted that claim 5, which of course is read as including the subject matter of its parent claim, does call for a focused ultrasound ablator disposed in the MRI examination region.

In the Examiner's comments addressing claims 8 and 13, it must be remembered that Schweikard specifically states in the paragraph starting at column 6, line 66, that the external markers, alone, lack sufficient accuracy. Using only external

markers would result in the safety margin of Figure 9B or 9C. Rather, the surgically implanted internal markers 152 must be used to achieve the results of Figure 9D sought by Schweikard.

In the Examiner comments addressing claims 9 and 14, the Examiner asserts that Schweikard discloses reference points / markers on the diaphragm and references sections of columns 2, 4, and 5. However, careful examination of these sections of Schweikard reveal that Schweikard makes no suggestion of reference points or markers on the diaphragm. The Examiner also asserts that external sensors on the motion / breathing region or chest region is the same as external sensors on the diaphragm. With even a basic understanding of human anatomy, one will understand that the diaphragm is internal, not external. Measuring movement of the diaphragm directly is not the same as measuring movement of the skin on the surface of the abdomen and the chest. External sensors on the abdomen and chest, which are the only type of sensors which Schweikard uses to model the respiratory cycle, move differently than the diaphragm due to other muscle movements, cardiac motion, fat layers, and the like. Because Schweikard does not monitor reference points / markers on the diaphragm, such points cannot be localized by a navigation processor in Schweikard. Moreover, the MR imaging referenced in Schweikard refers to the 3D planning images. Column 2, lines 42-44 of Schweikard references several technologies for determining the position of the external sensor, but magnetic resonance imaging is significant by its absence. (One can magnetically localize a marker which contains a magnet using one or more coils to measure changes in magnetic field strength, etc. No resonance or imaging is needed for magnetic localization). Accordingly, it is submitted that, contrary to the Examiner's assertion, claims 9 and 14 are not anticipated by Schweikard.

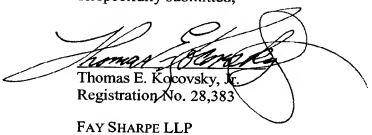
With regard to the Examiner's comments addressing claim 11, the appellant, like the Examiner, refers the reader to the preceding sections of this Brief. As indicated above, Schweikard does not disclose an MRI apparatus which both obtains images and localizes reference points disposed in proximity to a target.

CONCLUSION

For the reasons set forth in the Appeal Brief and for the additional reasons set forth above, it is submitted that claims 1-4, 6-9, and 11-14 are not anticipated by Schweikard and that claims 5, 10, and 15 distinguish patentably over Schweikard as modified by Aker.

An early reversal of all rejections is requested.

Respectfully submitted,



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